



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 107

[Docket No. FDA-2013-N-0067]

Infant Formula: The Addition of Minimum and Maximum Levels of Selenium to Infant Formula and Related Labeling Requirements; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of June 22, 2016, for the final rule that appeared in the Federal Register of June 23, 2015. The final rule amended the regulations on nutrient specifications and labeling for infant formula to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula.

DATES: Effective date of final rule published in the Federal Register of June 23, 2015 (80 FR 35834) confirmed: June 22, 2016.

FOR FURTHER INFORMATION CONTACT: Carrie Assar, Center for Food Safety and Applied Nutrition (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1451.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 23, 2015 (80 FR 35834), we amended the regulations on nutrient specifications and labeling for infant formula to

add 2.0 µg selenium per 100 kilocalories (/100 kcal) as the minimum level of selenium in infant formulas and 7.0 µg/100 kcal as the maximum level of selenium in infant formulas.

We gave interested persons until July 23, 2015, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the Federal Register of June 22, 2016, should be confirmed.

List of Subjects in 21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 350a, 371) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the June 23, 2015, final rule. Accordingly, the amendments issued thereby will become effective June 22, 2016.

Dated: October 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-25960 Filed: 10/9/2015 08:45 am; Publication Date: 10/13/2015]